



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

December 30, 2003

WARNING LETTER

NWE-15-04W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William G. Moynihan, President/Owner
Billy's Sandwiches Inc.
340 Samuel Gorton Avenue
Warwick, Rhode Island 02889

Dear Mr. Moynihan:

On November 20-24, 2003, a Food and Drug Administration (FDA) investigator inspected your seafood processing facility, located at 340 Samuel Gorton Avenue, Warwick, Rhode Island. We found that you have serious deviations from the seafood Hazard Analysis Critical Control Points (HACCP) regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your tuna salad subs are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The observed deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to

comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for tuna salad subs to control the food safety hazard of pathogen growth and toxin formation.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records for the eight (8) areas of sanitation required for the processing of tuna salad subs, as specified in 21 CFR 123.11(b).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operation.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as a completed HACCP plan, or other useful information that would assist in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello", written over the printed name.

Gail T. Costello
District Director
New England District